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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,497	09/30/2003	Mark S. Ortiz	END5135-0516315	4657
7590 01/04/2006			EXAMINER	
DAVID E. FRANKLIN FROST BROWN TODD LLC 2200 PNC CENTER 201 EAST FIFTH STREET CINCINNATI, OH 45202			POUS, NATALIE R	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 01/04/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/675,497	ORTIZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/22/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gifford et al. (US 6171321).

Regarding Claim 1, Gifford teaches a surgical instrument for implanting an anastomotic ring device, comprising: an actuating member configured to receive an anastomotic ring (104) and moveable between a cylindrical, unactuated position (Fig. 4) and a hollow rivet forming shape (Fig. 5c) in response to a compressive actuating force (127) a handle (133) including an actuation mechanism (132) for producing the compressive actuating force; and an elongate cannula connecting the handle to the actuating member and operably configured to transfer the compressive actuating force from the handle to the actuating member.

Regarding Claim 5, Gifford teaches the surgical instrument of claim 1, further comprising a piercing tip (136) distally coupled to the actuating member.

Regarding Claim 6, Gifford teaches the surgical instrument of claim 5, wherein the piercing tip (136) comprises an enterotomy creation tip. It is noted that according to Merriam Webster, the following is the definition of enterotomy: incision into the

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intestines. It is asserted that the piercing head (136) is capable of creating an incision in the intestines.

Regarding Claim 13, Gifford teaches a surgical instrument, comprising: a cannula (125); an actuating member (127) distally and laterally presented on the cannula for receiving a generally cylindrical anastomosis ring (101); and a first control (142) operative to compress a longitudinal end of the actuating member toward a center of the actuating member to actuate a respective portion of the received anastomosis ring.

Regarding Claim 16, Gifford teaches the surgical instrument of claim 13, further comprising an enterotomy creation tip distally coupled to the cannula. It is noted that according to Merriam Webster, the following is the definition of enterotomy: incision into the intestines. It is asserted that the piercing head (136) is capable of creating an incision in the intestines.

Claims 1-4, 13 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Suyker et al (US 6485496).

Regarding Claim 1, Suyker teaches a surgical instrument for implanting an anastomotic ring device, comprising: an actuating member (14) configured to receive an anastomotic ring (1) and moveable between a cylindrical, unactuated position (Fig. 7) and a hollow rivet forming shape (Fig. 20) in response to a compressive actuating force a handle (44) including an actuation mechanism (45) for producing the compressive actuating force; and an elongate cannula (40) connecting the handle to the actuating

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member and operably configured to transfer the compressive actuating force from the handle to the actuating member.

Regarding Claim 2, Suyker teaches the surgical instrument of claim 1, wherein the handle is further operably configured to produce the compressive actuating force by producing a proximally directed longitudinal motion and a distally directed longitudinal motion (Column 7, proximate lines 5-36), the elongate cannula operably configured to separately transfer the proximally and distally directed longitudinal motions respectively to distal (46) and proximal (41) portions of the actuating member.

Regarding Claim 3, Suyker teaches the surgical instrument of claim 2, wherein the elongate cannula comprises a first tube (40) connected to the proximal portion of the actuating member (41) and a second tube (37) slidably received in the tube and connected to the distal portion of the actuating member.

Regarding Claim 4, Suyker teaches the surgical instrument of claim 3, wherein the elongate cannula further comprises a third tube (44) interposed between the first and second tubes and distally engaged to a central portion of the actuating member (38).

Regarding Claim 12, Suyker teaches a surgical instrument, comprising: a means for inserting an anastomotic ring device (1) to tissue walls of two lumens; an actuating means (14) for transforming the anastomotic ring device from a generally circular shape to a hollow rivet shape.

Regarding Claim 13, Suyker teaches a surgical instrument, comprising: a cannula (44); an actuating member (14) distally and laterally presented on the cannula

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for receiving a generally cylindrical anastomosis ring (1); and a first control operative to compress a longitudinal end of the actuating member toward a center of the actuating member to actuate a respective portion of the received anastomosis ring.

Regarding Claim 14, Suyker teaches the surgical instrument of claim 13, further comprising: a second control (45) operative to compress another longitudinal end of the actuating member (46) toward the center of the actuating member to actuate the other respective portion (20) of the received anastomosis ring (1).

Regarding Claim 15, Suyker teaches the surgical instrument of claim 13, further comprising a stationary member (38) mechanically grounding the center of the actuating member relative to the first cannula.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 11, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford in view of Yeatman (US 6451029).

Gifford discloses all aspects of preceding dependent claim 1 but fails to disclose wherein the instrument comprises a pneumatic conduit communicating between the distal tip and the handle for inflating a body lumen, and the tip comprising a veress needle. Yeatman teaches an intestinal stapling device wherein a pneumatic conduit (26) is in communication with the distal tip and handle (30) in order to provide a means of leak testing and performing anastomosis with a common instrument. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Gifford with a pneumatic conduit communicating between the distal tip and the handle for inflating a body lumen in order to provide a means of leak testing and performing anastomosis with a common instrument.

Regarding the limitation wherein the piercing tip comprises a veress needle, it is noted that a veress needle is one which serves to insufflate a body cavity for a laparoscopic procedure. It is further noted that the combination of Gifford and Yeatman as described above fulfills that description, and therefore fulfills the structure and function of a veress needle.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Gifford and further in view of Yeatman. Suyker teaches all aspects of preceding dependent claims 13 and 14 as previously described, but fails to teach wherein the device comprises a veress needle enterotomy creation tip. Gifford teaches an anastomosis device comprising an enterotomy creation tip (136) in order to puncture

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the tissue and implant the anastomosis ring with the same tool. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the anastomosis device of Suyker with an enterotomy creation tip as taught by Gifford in order to puncture the tissue and implant the anastomosis ring with the same tool.

Yeatman teaches a medical device wherein a pneumatic conduit (26) is in communication with the distal tip and handle (30) in order to provide a means of leak testing and performing anastomosis with a common instrument. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Suyker and Gifford with a pneumatic conduit in communication with the distal tip and handle in order to provide a means of leak testing and performing anastomosis with a common instrument. It is noted that a veress needle is one which serves to insufflate a body cavity for a laparoscopic procedure. It is further noted that the combination of Suyker, Gifford and Yeatman as described above fulfills that description, and therefore fulfills the structure and function of a veress needle.

Claims 8, 9, 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Toledano (US 5855312). Suyker teaches all aspects of preceding dependent claims 1 and 13 as previously described, but fails to disclose wherein the instrument comprises an illumination source connected to the cannula proximate to the distal portion of the actuating member, the actuating member comprises a light transmissive material. Toledano teaches a medical stapling device wherein actuating member (11) comprises an optical fiber bundle (71) connected to the



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cannula and terminates in a translucent light transmissive head (25) in order to emanate light from the end of the device and illuminate the surrounding tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the actuating member of Suyker with an illumination source connected to the cannula proximate to the distal portion of the actuating member, the actuating member comprising a light transmissive material as taught by Toledano in order to emanate light from the end of the device and illuminate the surrounding tissue.

The limitation wherein the actuating member comprises an electroluminescent material, is rejected as unpatentable over the combination of Suker and Toledano as a matter of design choice. It would have been obvious matter of design choice to modify the combination of Suker and Toledano by having the actuating member comprise an electroluminescent material since it appears the translucent material would perform equally well to illuminate the surrounding tissue as electroluminescent material.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP  
12/20/05

*Carlyemlike*  
primary examiner  
Art unit 3731